



Ranking of expensive drugs based on cost-utility ratios prior to coverage decision-making on therapeutic programs of the National Health Fund in Poland

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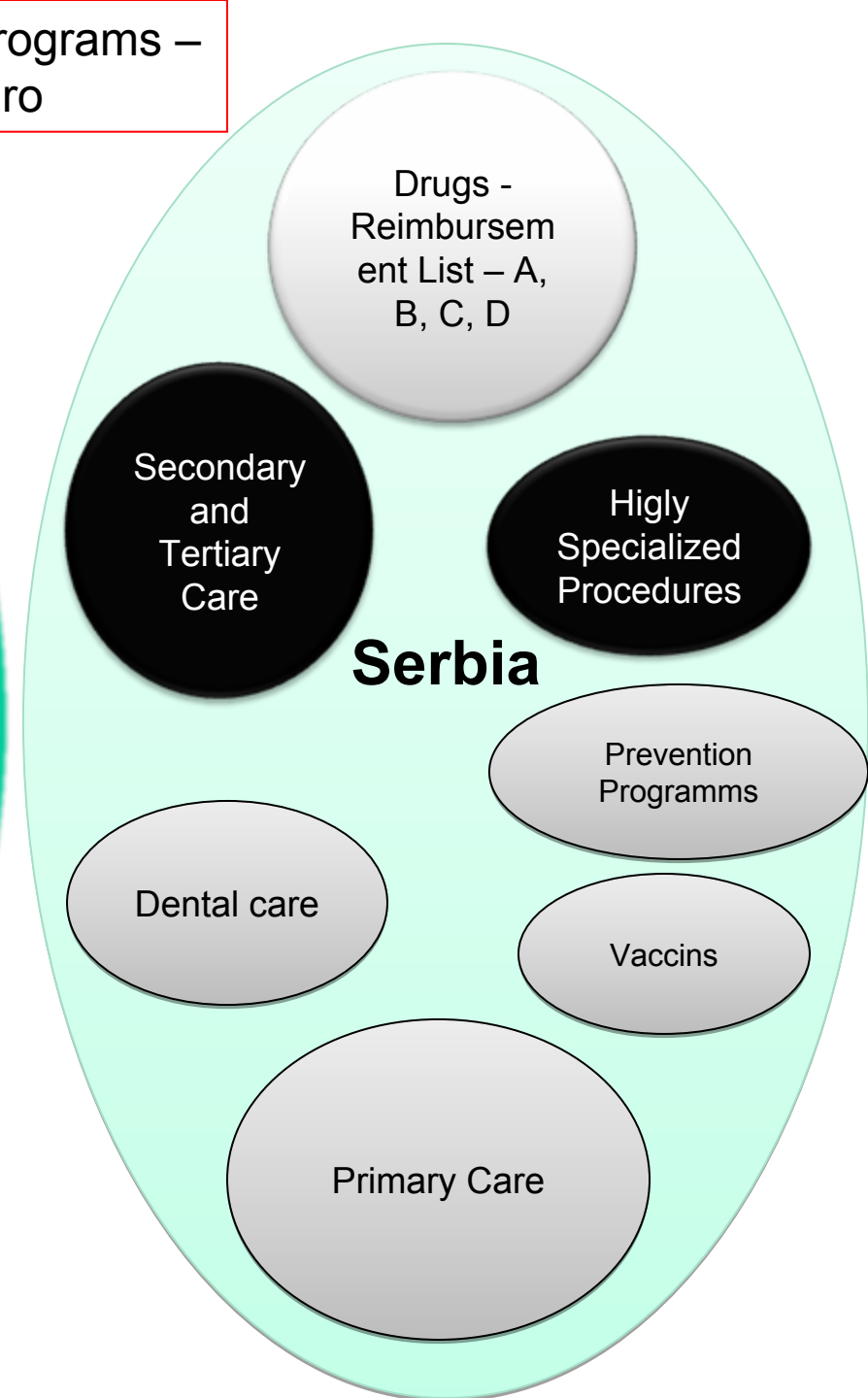
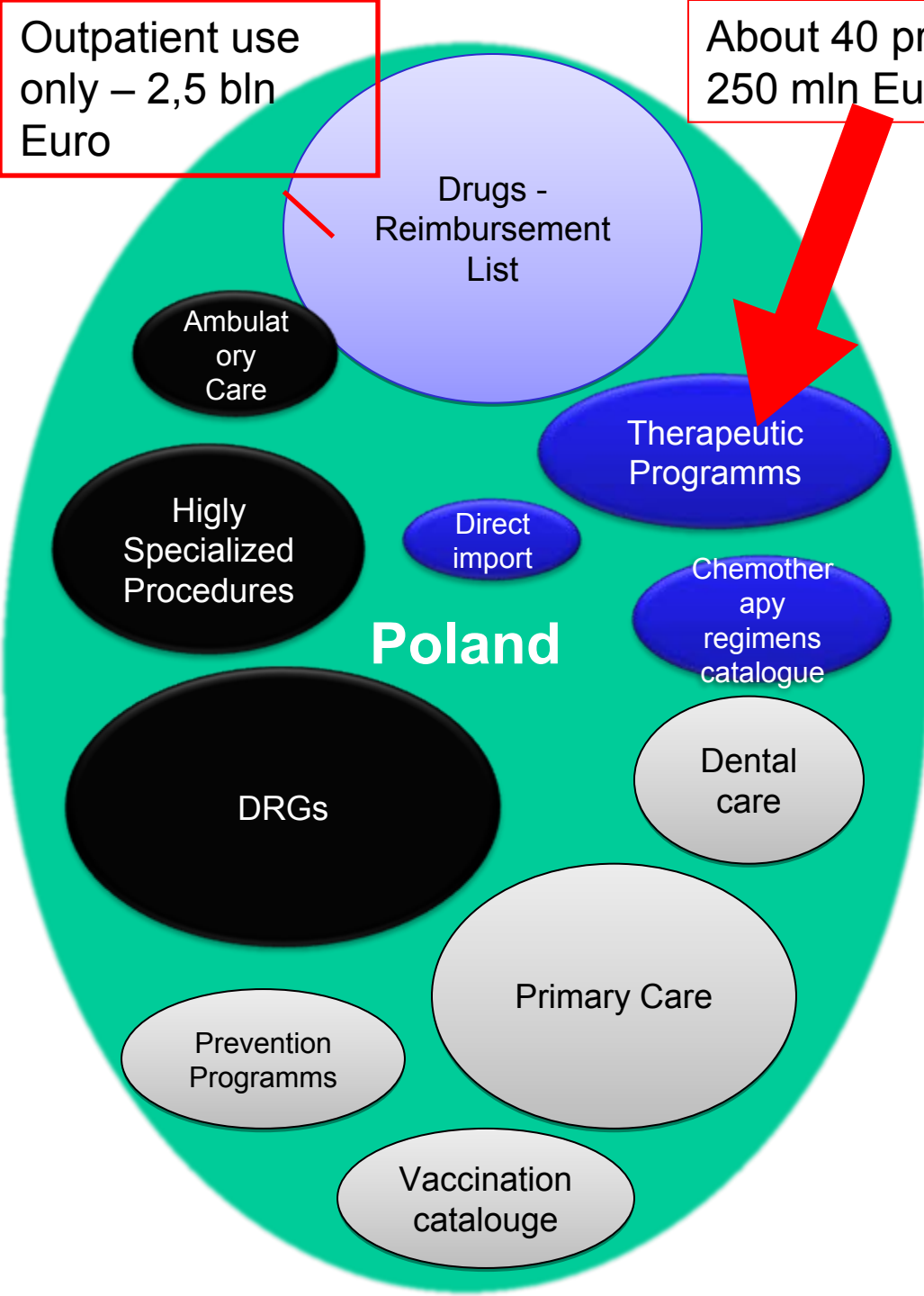


Background shortly

- 2003 –a founding member of Central & Eastern European Society of Technology Assessment in Health Care (CEESTAHC)
- 2001-2006 – the CEO of HTA Consulting – development of more than 80 full HTA reports
- 2004-2007 - member of the Board of Directors of Health Technology Assessment International (HTAi)
- 2006-2007 - consultations for the Ministry of Health in Serbia within a World Bank project
- **2006-2007 Director of the Drug Policy Department of the National Health Fund in Poland**
- currently the Team Leader of the World Bank project on systemic implementation of HTA in Serbia and consultancy in a company „HTA Audit”

Outpatient use only – 2,5 bln Euro

About 40 programs – 250 mln Euro





Expensive drugs in Poland may be covered from the following parts of BBP:

- 1. Therapeutic programs (separate budget of NHF)**
2. Drug reimbursement list (out patient use only; separate budget of NHF)
3. List of chemotherapy agents (within contracted hospital budget)
4. Hospital use due to DRGs (within contracted hospital budget)
5. Direct import (drugs not registered in EU; separate small budget of NHF)



What does a decision-maker want to know?

1. Is this technology of **proven efficacy** and what is its safety profile?
2. What is the **strength of intervention** in comparison to optional ones? (which is the most efficacious option and what are the differences)
3. Which is the **most cost-effective option** and what are the differences?
4. **Budget impact:** Is coverage of the intervention possible in respect to available resources? What changes should we expect if the technology gets a privileged market position?



Legal foundations and current coverage decision-making in Poland

1. Law on health services – required analyses clearly listed
2. **Decree no 17/2007** and 38/2007 of the NHF President on so called therapeutic programs – referring for quality requirements to the HTA guidelines
3. **Guidelines for HTA** – formal assessment by the Polish HTA Agency or NHF or MoH
4. Appraisal by Advisory Council, or independently by MoH or NHF



Coverage criteria

1. **Proven efficacy & fair safety profile**
2. **Cost-effectiveness or cost-utility ratio**

(that embraces importance of health problem and strength of intervention – therefore no prioritization or other weights with that respect needed)

„**Project risk**” – risk of taking a wrong coverage decision (uncertainty around estimates) -> RANKING

BIA only for calculation of the cumulative budget spending and drawing a general threshold of affordability



Rigorousness differs

Due to a unit price or/and budget impact health technologies (including drugs) can be classified as:

1. CHEAP
2. EXPENSIVE
3. VERY EXPENSIVE

Therefore requirements for set of analyses, acceptable „project risk” and rigorousness in appraisal vary in different parts of BBP



Therapeutic programs (TPs)

- **Separate NHF budget for usually very expensive drug and non drug technologies**
- **Rare and ultrarare diseases; limited number population (prevalence up to 7000 persons)**
- **Clear inclusion & exclusion criteria based on HTA introduced in mid 2007 – the decree of the NHF President no. 17/2007 and 38/2007**



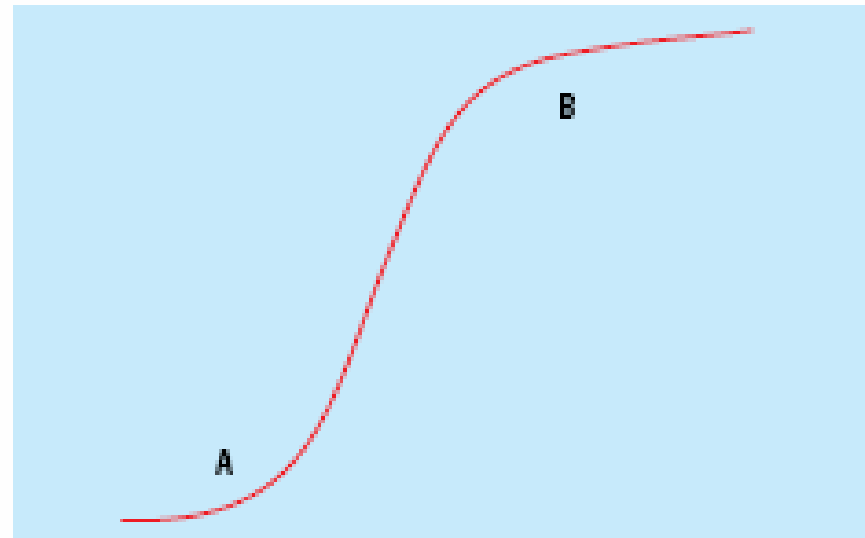
Ranking of TPs

- The third quarter of 2006 and the first of 2007 – catalogue of **180 applications**;
- Mid 2007 – ranking of applications based strongly on **cost-utility** but taken into account other factors („project risk”) and showing cumulated budget impact
- Assumptions of: resources to be spent are limited, no waiting lists for the entitled patients with a given and well defined condition, careful monitoring/rigorous reporting similar to clinical trials – strict clinical and cost registries due to proposed GRP



BMJ publication on cost-effectiveness thresholds by Prof. Sir Michael Rawlins

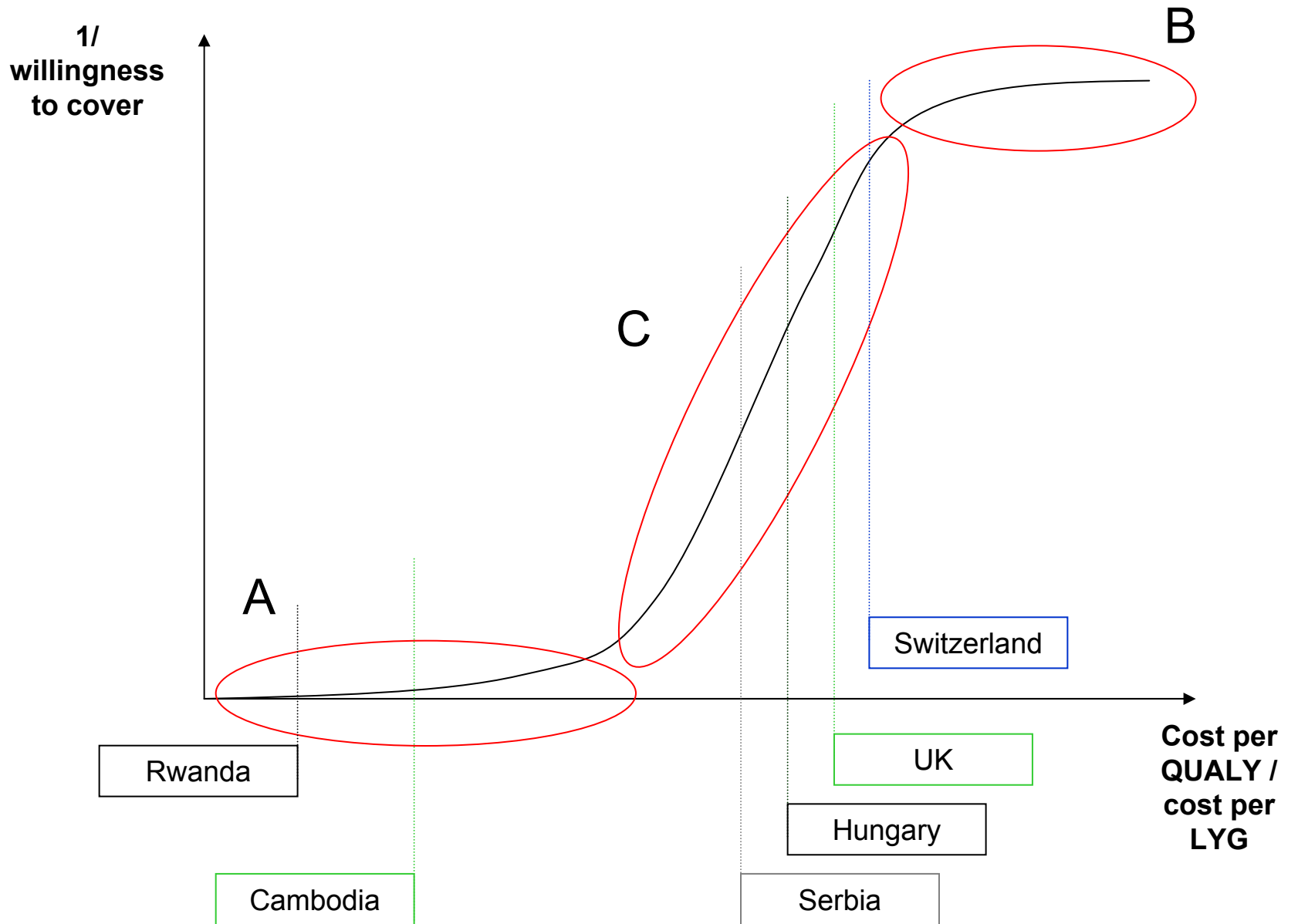
Probability of rejection on grounds of cost ineffectiveness



Increasing cost/QALY (log scale)

National Institute for Clinical Excellence and its value judgments

Michael D Rawlins, Anthony J Culyer





CU/CE thresholds

3x GDP / person per 1 LYG or 1 QUALY (WHO per 1 DALY)

Poland – about 18 000 £ (23 500 €)

Serbia – about 11 000 £ (14 500 €)

NICE: ***UK cannot effort 3xGDP per 1 QUALY***

UK – 30 000 £ (39 000 €)

but now even less 20 000 £ (26 000 €)



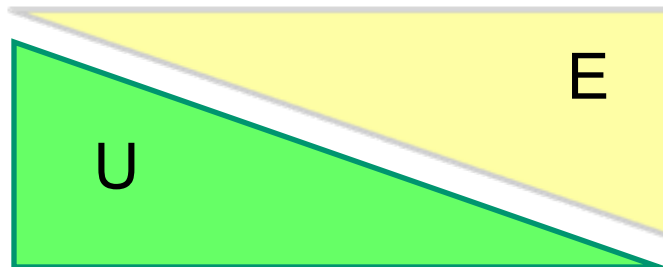
Reimbursement criteria – **utilitarian**, **egalitarian** or **mixed** approach?

**“COMMON”
DISEASES**

**RARE
DISEASES**

**ULTRARARE
DISEASES**

**Utilitarian
approach**



**Egalitarian
approach**



Analytic requirements for expensive health technologies

Expensive technology = high unit cost / price and/or substantial impact on the payer's budget

Utilitarian approach	Egalitarian approach
Efficacy and safety analysis based on a systematic review	Efficacy and safety analysis based on a systematic review
Economic analysis (CEA, CUA, CMA)	PRICE JUSTIFICATION
BIA	BIA



Ranking in the 2 out of 4 subsets of applications

1. with potential to cut costs of NHF in a given condition → SEPARATE SUBSET FOR RANKING
2. increasing total costs of NHF but with good quality HTAs submitted → SEPARATE SUBSET FOR RANKING
3. applications with HTAs but missing important pieces of information – INFORMATION TO BE COMPLETED OR OTHERWISE REJECTED
4. rejected due to lack of validity, completeness or proper information due to HTA guidelines in Poland - REJECTED



CE thresholds do not apply to technologies to treat ultrarare and rare diseases but still allow for ranking within the part of BP

$\Delta C \times 40$

Authors of the ranking card: Krzysztof Łanda and Wojciech Wysoczański, NHF Central Office

$\Delta U \times (II+III+IV+V) \times VI$

- ΔC incremental cost
- ΔU incremental utility
- II impact on the patient's health (the highest grades for end-of-life diseases and ultrarare diseases)
- III impact on public health (the highest grades for communicable diseases)
- IV additional aspects (orphan status, social expectations: patients, physicians etc.)
- VI uncertainty around estimates (evaluation of probability that the costs will not be higher and the effects not lower than presented in the analyses; grades from 0 to 1)



Results of BIA do NOT apply as a ranking criterion

BIA only for calculation of the cumulative budget spending

If assumption that extra 300 mln Euros are available

VI	Ranking score (thousands Euro / QALY)	Place in the ranking	BIA / mln Euro	Cumulative BIA / mln Euro
0.9	20	1	23	23
0.75	28	2	3	26
0.82	41	3	35	61
0.92	66	4	170	231
0.6	80	5	125	356 (RSS?)
0.67	120	6	15	371
0.78	170	7	8	



Ranking was actually taken as a part of appraisal process

Ranking was only one element taken into account in decision-making

Decision-taking merely reflected ranking results

Ranking abandoned in the NHF; all applications have been sent for appraisal to HTA Agency and the Consultancy Council from September 2007 till now



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Thank you